UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

ELI LILLY AND COMPANY, et al.,

Plaintiffs,

v. Case No. 17-C-703

ARLA FOODS INC. d/b/a
ARLA FOODS INC. USA, et al.,

Defendants.

DECISION AND ORDER GRANTING IN PART AND DENYING IN PART MOTION FOR PRELIMINARY INJUNCTION

Plaintiffs Eli Lilly and Company and Elanco US Inc. (collectively "Elanco") filed this action seeking a preliminary injunction against Defendants Arla Foods Inc., USA and Arla Foods Production LLC (collectively "Arla"). Elanco asserts that Arla's recently launched "Live Unprocessed" advertising campaign makes false and misleading statements regarding recombinant bovine somatotropin ("rbST")—a supplement produced and sold by Elanco under the brand name Posilac®—in violation of the Lanham Act, 15 U.S.C. § 1125(a), and Wisconsin Statute § 100.20(1). On June 7, 2017, the court held a hearing on Elanco's motion for a preliminary injunction. For the reasons given below, the motion will be granted in part and denied in part.

BACKGROUND

Elanco is in the business of developing and marketing products that aim to improve animal health and food production worldwide. At issue in this case is Posilac®, Elanco's rbST supplement and one of its top five selling products. Bovine somatotropin ("bST") is a naturally occurring hormone in the pituitary glands of cattle which funnels nutrients toward the production of milk.

rbST is a genetically engineered version of bST that has been designed to prolong the lactation period of dairy cows and increase milk production.

rbST was originally developed and marketed in the 1980s. The Food and Drug Administration ("FDA") conducted an in-depth review of the scientific evidence regarding the composition and safety of dairy products made with milk from cows treated with rbST. On November 5, 1993, the FDA approved Posilac® and concluded that rbST "is safe and effective for dairy cows, that milk from rbST-treated cows is safe for human consumption, and that production and use of the product do [sic] not have a significant impact on the environment." 59 Fed. Reg. 6279, 6279–80 (Feb. 10, 1994). In an effort to prevent any misleading implications about the safety of rbST, the FDA noted that "accompanying the statement 'from cows not treated with rbST' with the statement that 'No significant difference has been shown between milk derived from rbST-treated and non-rbST treated cows' would put the claim in proper context." *Id.* at 6280. Since the approval of the sale of Posilac®, the FDA and the Joint Food and Agriculture Organization of the United Nations ("FAO")/World Health Organization ("WHO") Expert Committee on Food Additives ("JECFA") have reexamined possible health risks posed by milk from rbST-treated cows based on new scientific literature. JECFA and the FDA most recently reviewed Posilac® in 2014 and 2016 respectively and confirmed the FDA's previous determination that rbST is safe and effective for its intended use.

Posilac® is the only FDA-approved rbST supplement. In 2008, Elanco purchased the exclusive U.S. rights to market and produce Posilac®. Elanco sells Posilac® directly to dairy farmers and producers. The farmers then treat their cows with rbST and sell the milk to dairy suppliers and processors to prepare the fluid milk for distribution. The suppliers then sell the fluid

milk to manufacturers who prepare the treated milk for a consumer facing product, such as cheese or yogurt. The product is then sold to retailers, like supermarkets, where the consumer ultimately purchases the finished product.

Arla Foods is a Denmark-based large dairy cooperative and is owned by more than 12,000 farmers in seven countries. Arla asserts that its business model is based in part on "Arlagården®," a farm quality assurance program with four cornerstones: 1) milk composition, 2) food safety, 3) animal welfare, and 4) environmental considerations. In the United States, Arla markets a variety of cheese and cream cheese products to retail outlets such as Costco, Sam's Club, and Kroger.

On April 25, 2017, Arla launched its first fully integrated U.S. brand campaign: "Live Unprocessed™." The accompanying press release noted that the $30 million campaign was designed to "resonate with today's 'ingredient savvy' consumer" and "comes at a tipping point of Americans' increasingly voracious desire to know more about the products they're eating and feeding their families." ECF No. 5-5. "The campaign asked kids what—or who—they thought r[b]ST, xanthan and sorbic acid were, without letting them know that they were ingredients often found in sliced and cream cheeses. The kids were partnered with animators who brought their fantastical stories and drawings to life in two 30-second commercials." *Id.* The campaign features a television buy across more than 20 national cable networks, advertisements in print and digital media, in-store advertising, social media outreach, promotional videos, and a website.

A key component of Arla's advertising campaign is a 30-second commercial: "Arla Cheese Asked Kids: What is r[b]ST?" The commercial is based around Leah, a seven-year-old girl, explaining what she thinks rbST is. The commercial opens with an animated depiction of a large six-eyed monster, which Leah explains has razor sharp teeth and is so tall that it can eat clouds. Leah

cautions that although you may want to pet the monster, its fur is electric. A fisherman is electrocuted while touching the monster and falls down a hill, during which the monster and Leah laugh. The commercial then abruptly shifts to an in-person look at Leah in a bright room, drawing a picture of the monster. The narrator explains that "Actually rbST is an artificial growth hormone given to some cows, but not the cows that make Arla cheese. No added hormones. No weird stuff." At the bottom of the screen is a small disclaimer: "Made with milk from cows not treated with r[b]ST. No significant difference has been shown between milk derived from r[b]ST-treated cows and non-r[b]ST-treated cows." The commercial ends with Leah happily eating a sandwich made with Arla cheese. The commercial is currently airing on several cable channels such as the Food Network, the Hallmark Channel, Bravo, and Lifetime.

Arla's "Live Unprocessed" campaign also involves an active digital and social media presence. The commercial at issue has been posted on its Twitter, Facebook, Instagram, and YouTube pages. A constant refrain throughout the campaign is that Arla cheese has "no weird stuff." Arla defines "weird stuff" on its website:

> No artificial additives. No ingredients that you can't pronounce. No ingredients that sound confusing or in any way like a made-up word. No ingredients with names that sound like they may be aliens with nine arms, beasts with electric fur, gigantic robots or bears in disguise. No artificial growth hormones like r[b]ST.* No ingredients that might be misinterpreted as medium-sized slime balls, whales with a mustache and wearing a little hat, witches with wings or the smallest birds ever and that shoots lightening from its wings. Also, no artificial preservatives. Nor anything else artificial, because our cheese has always been made with simple ingredients and never anything weird.

Let's Simplify Our Food. Let's Simplify Our Lives., ARLA USA, https://www.arlausa.com/liveunprocessed (last visited June 15, 2017). The asterisk directs visitors to the bottom of Arla's web page to its disclaimer that "No significant difference has been shown

between milk derived from rbST-treated and non-rbST-treated cows." *Id.* Arla's website also suggests that its dairy products are something "you can feel good about eating and serving to your friends and family." *Id.*

Elanco contends that Arla's "Live Unprocessed" advertising campaign violates the Lanham Act and Wisconsin Statute § 100.20(1) because it makes false and misleading representations of fact concerning the composition, health, and safety of dairy products made using milk from rbST-treated cows. A hearing on Elanco's motion for a preliminary injunction was held on June 7, 2017. Elanco presented expert testimony and other evidence to support its contention that milk from cows treated with rbST is nearly identical to the composition of milk from non-rbST–treated cows and there are no health or safety risks posed by rbST to either the cows or humans. Elanco also argued that, as the only producer of an FDA-approved rbST supplement, it has and will continue to experience irreparable harm. It claimed at least one major cheese producer has notified Elanco that the producer will eliminate its use of milk from rbST-treated cows within the next year, at least in part due to Arla's campaign. Elanco further asserts it is experiencing reputational damage simply based upon Arla's false implication about the safety of rbST. Elanco requests that this court enjoin Arla from continuing to make false representations about rbST during the pendency of this action and order corrective advertising to address more than a month's worth of false advertising.

ANALYSIS

I. Arla's Motion to Strike

As an initial matter, Arla filed a motion to strike the supplemental declaration of Grady Bishop and each of its attached exhibits. Arla asserts that the declaration was untimely, the material was available at the time Elanco filed its original motion, and that the untimely submission deprived

Arla of a fair opportunity to respond. However, the declaration was in direct response to Arla's argument that Elanco lacked standing to assert a Lanham Act claim, an argument Elanco reasonably did not anticipate, and Arla had the opportunity to cross-examine Mr. Bishop about the accuracy and veracity of his declaration and the exhibits attached to it at the June 7, 2017 hearing. Additionally, Arla has not pointed to any harm it suffered from the late filing or suggested any evidence it would have offered in response had it been disclosed earlier. For these reasons, I conclude that Arla was not prejudiced and its motion to strike will be denied.

II. Standing

Arla argues Elanco lacks standing to bring its claims under the Lanham Act and Wisconsin law. A plaintiff seeking to assert a false advertising claim under § 1125(a) must allege "an injury to a commercial interest in sales or business reputation proximately caused by the defendant's misrepresentations." *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 134 S. Ct. 1377, 1395 (2014). Arla claims any connection between its advertising campaign and injury to Elanco is simply too tenuous to establish Lanham Act standing. Arla asserts that in order for the "Live Unprocessed" campaign to harm Elanco: (1) cheese consumers must see the advertisement and determine they no longer wish to purchase cheese from cows treated with rbST; (2) enough consumer feedback forces cheese manufacturers to reevaluate where they get their dairy products; (3) those manufacturers in turn force dairy suppliers to change their business model; (4) the dairy suppliers then inform the dairy farmers they will not buy fluid milk from cows treated with rbST; and (5) the farmers finally inform Elanco they will no longer purchase Posilac®, the rbST supplement. Based on the recency of the advertising campaign and the allegation that rbST sales have been in decline for several years, Arla

argues it is too speculative to suggest that any economic or reputational injury suffered by Elanco flows directly from Arla's advertising.

Lexmark is the most recent Supreme Court case to address the issue of Lanham Act standing. Lexmark, a manufacturer and retailer of computer printing products, sold printer toner cartridges in direct competition with "remanufacturers" that acquired used Lexmark cartridges, refurbished them, and sold them to consumers. *Id.* at 1383. Lexmark sought to maintain its market share by installing microchips in its cartridges to deactivate them when empty and thereby prevent competitors from refurbishing empty cartridges. Static Control subsequently developed a comparable microchip which allowed the remanufacturers to once again refurbish and resell used Lexmark cartridges. *Id.* at 1384. Lexmark sued Static Control for copyright infringement. Static Control filed a false advertising counterclaim under the Lanham Act, alleging Lexmark had engaged in a mass advertising campaign that suggested consumers were required to return empty printer cartridges directly to Lexmark and that Static Control's products were illegal. *Id.* Lexmark challenged Static Control's standing to maintain a false advertising counterclaim under the Lanham Act. *Id.* The Supreme Court granted certiorari to determine "the appropriate analytical framework for determining a party's standing to maintain an action for false advertising under the Lanham Act." *Id.* at 1385.

The Court framed the issue as "whether Static Control falls within the class of plaintiffs whom Congress has authorized to sue under § 1125(a)." *Id.* at 1387. It began its analysis by recognizing that the statute is ostensibly broad, authorizing "any person who believes that he or she is likely to be damaged" by a defendant's false advertising to bring suit. 15 U.S.C. § 1125(a)(1). The Court concluded it was unlikely that Congress meant to permit anyone who can satisfy the minimum

requirements of Article III standing to bring an action under § 1125. *Lexmark*, 134 S. Ct. at 1387. It construed the statute more narrowly and found that only those plaintiffs who fell within the statutory zone of interests and established proximate causation may bring suit under § 1125(a). *Id.* at 1388. A plaintiff falls within the statutory zone of interests in a suit for false advertising under § 1125(a) when he alleges "an injury to a commercial interest in reputation or sales." *Id.* at 1390. As for establishing proximate cause, the Court acknowledged that the harm alleged must have a "sufficiently close connection to the conduct the statute prohibits." *Id.* Accordingly, a plaintiff must show "economic or reputational injury flowing directly from the deception wrought by the defendant's advertising." *Id.* at 1391. This showing, however, is "generally not made when the deception produced injuries to a fellow commercial actor that in turn affect the plaintiff." *Id.*

Applying these principles, the Court held that Static Control had Lanham Act standing to assert its false advertising claim, despite the fact that it was not one of Lexmark's direct competitors. The Court reasoned, when a plaintiff "claims reputational injury from disparagement, competition is not required for proximate cause." *Id.* at 1394. This is true even if "the defendant's aim was to harm its immediate competitors, and the plaintiff merely suffered collateral damage." *Id.* Justice Scalia compared the situation to two rival carmakers that use airbags created by different third-party manufacturers:

> If the first carmaker, hoping to divert sales from the second, falsely proclaims that the airbags used by the second carmaker are defective, both the second carmaker and its airbag supplier may suffer reputational injury, and their sales may decline as a result. In those circumstances, there is no reason to regard either party's injury as derivative of the other's; each is directly and independently harmed by the attack on its merchandise.

Id. The Court noted that if the remanufacturers sold 10,000 fewer refurbished cartridges because of Lexmark's false advertising campaign, it would follow that Static Control sold 10,000 fewer microchips for the same reason. *Id.* Although the causal chain linking Static Control's injuries to consumer confusion was not direct, the Court concluded Static Control alleged an adequate basis to proceed under § 1125(a) of the Lanham Act. *Id.* at 1394–95.

In this case, Elanco's allegations are sufficient to establish Lanham Act standing despite the number of intervening parties between it and the consumers which Arla's campaign seeks to reach. Arla's commercial centers around what children think rbST is and begins with a depiction of rbST as a scary monster. Elanco alleges Arla's portrayal of rbST as a deadly monster or its claim that rbST is "weird stuff" is false. Am. Compl., ECF No. 10, ¶¶ 46, 48. "[A] defendant who 'seeks to promote his own interests by telling a known falsehood to *or about* the plaintiff or his product' may be said to have proximately caused the plaintiff's harm." *Lexmark*, 134 S. Ct. at 1393–94 (citations omitted) (emphasis in original). While the commercial does not mention Elanco or Posilac®, Elanco produces the only FDA-approved rbST supplement on the market. An alleged reputational attack on rbST is necessarily a reputational attack on Posilac®, one of Elanco's major products. Elanco has provided evidence that Arla's advertisements result in economic injuries as well. Shortly after the Arla campaign began, at least one major cheese producer notified Elanco that it would transition to rbST-free cheese effective mid-2018 and noted Arla's commercials were a major consideration that led to its decision. ECF No. 30-6. Furthermore, an Arla declaration noted that one of the "most important factors leading to disadoption of rbST" was "fears about negative public opinion." An Decl., ECF No. 25-3, at ¶ 18. All of the allegations taken together are sufficient to conclude that Elanco has Lanham Act standing.

Arla also argues that Elanco failed to establish Article III standing. A plaintiff seeking to invoke a federal court's jurisdiction must demonstrate that he has suffered or is "imminently threatened with a concrete and particularized 'injury in fact' that is fairly traceable to the challenged action of the defendant and likely to be redressed by a favorable judicial decision." *Lexmark*, 134 S. Ct. at 1386 (citing *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992)). Here, Arla asserts that because Arla and Elanco are not competitors and the campaign makes no explicit or implied reference to Elanco or its products, Elanco has failed to show that its injuries are "fairly traceable" to Arla's advertising. Again, allegations that a false advertisement damages the reputation of the plaintiff's product is enough to establish that the defendant proximately caused the reputational harm. *Id.* at 1393. Elanco alleged that it suffered both reputational and economic harm as a result of Arla's advertising campaign and will continue to be injured while the advertising continues. These allegations are sufficient to establish that Elanco has suffered, or is at least imminently threatened with, a concrete and particularized injury that is fairly traceable to Arla's advertising campaign. In sum, I am satisfied that Elanco has fulfilled the requirements for both Lanham Act and Article III standing in this matter.

Finally, Arla makes a similar challenge to Elanco's standing to assert its claims under Wisconsin law. Wisconsin Statute § 100.20 states, "Any person suffering pecuniary loss because of a violation by any other person of any order issued under this section may sue for damages therefor in any court of competent jurisdiction and shall recover twice the amount of such pecuniary loss, together with costs, including a reasonable attorney's fee." § 100.20(5). Arla argues Elanco has failed to show a "causal connection" between Arla's advertisements and labels and Elanco's supposed pecuniary loss in sales. Def.'s Br. in Opp'n, ECF No. 25, at 19–20 (citing *Grand View*

Windows, Inc. v. Brandt, 349 Wis. 2d 759, 774, 837 N.W.2d 611 (Ct. App. 2013) ("[A] party asserting a pecuniary loss for the purposes of Wis. Stat. § 100.20(5) must show that there is a causal connection between a prohibited trade practice . . . and the damage incurred.")). Again, Elanco has alleged that Arla's advertising campaign proximately caused its pecuniary harm. This is sufficient to establish standing to assert a claim under Wis. Stat. § 100.20. Having determined that Elanco has standing to bring this lawsuit, the court now turns to the merits of Elanco's motion for a preliminary injunction.

III. Elanco's Motion for a Preliminary Injunction

A preliminary injunction is an "extraordinary and drastic remedy," that should only be granted when the movant makes a clear showing demonstrating he is entitled to relief. *Mazurek v. Armstrong*, 520 U.S. 968, 972 (1997) (citation omitted); *see also Korte v. Sebelius*, 735 F.3d 654, 703 (7th Cir. 2013). To obtain a preliminary injunction, the moving party must show that it has "(1) no adequate remedy at law and will suffer irreparable harm if a preliminary injunction is denied and (2) some likelihood of success on the merits." *Ezell v. City of Chicago*, 651 F.3d 684, 694 (7th Cir. 2011). If this showing is made, "the court weighs the competing harms to the parties if an injunction is granted or denied and also considers the public interest." *Korte*, 735 F.3d at 665.

Arla claims Elanco failed to establish a reasonable likelihood of success on the merits because the advertisement does not allege that rbST is unhealthy or unsafe. To the extent that the commercial does make those representations, Arla argues it is neither false nor misleading because the safety of rbST remains an open scientific debate. Finally, Arla claims Elanco failed to show irreparable harm and that the balance of harms and public interest weigh against a preliminary injunction. The court will address each argument in turn.

A. Likelihood of Success: the Lanham Act

Elanco seeks relief under the Lanham Act for what it views as Arla's "false or misleading misrepresentations of fact" in its advertising campaign. 15 U.S.C. § 1125(a)(1). "In order to establish a claim of false or deceptive advertising under § 43(a) of the Lanham Act, a plaintiff must show that the defendant made a material false statement of fact in a commercial advertisement and that the false statement deceived or had the tendency to deceive a substantial segment of its audience." *Muzikowski v. Paramount Pictures Corp.*, 477 F.3d 899, 907 (7th Cir. 2007). "Where the statement in question is actually false, then the plaintiff need not show that the statement either actually deceived consumers or was likely to do so. But where the statement is literally true or ambiguous, then the plaintiff is obliged to prove that the statement is 'misleading in context, as demonstrated by actual consumer confusion.'" *B. Sanfield, Inc. v. Finlay Fine Jewelry Corp.*, 168 F.3d 967, 971–72 (7th Cir. 1999) (citations omitted).

1. Health/Safety of milk from rbST-treated and non-rbST–treated cows

For the purposes of this motion, the court must first determine whether there are any compositional or safety differences between milk produced by rbST-treated and non-rbST–treated cows. If milk from rbST-treated cows is less safe than milk from non-rbST–treated cows, it would not necessarily be false or misleading to imply this fact in, say, a television commercial. If, however, treated and non-treated cows produce the same quality of milk, suggesting otherwise could constitute false or misleading misrepresentations of fact under the Lanham Act.

Arla argues "a representation in an advertisement cannot be false where 'the scientific evidence [regarding the product in issue] is equivocal.'" Def.'s Br. in Opp'n at 21 (citing *In re GNC Corp.*, 789 F.3d 505, 516 (4th Cir. 2015)). It asserts that, here, the scientific community has not yet

reached a consensus on the safety of rbST and widespread evidence exists demonstrating that "the use of rbST leads to adverse health effects for the dairy cattle, lower quality milk, and potential adverse human health effects." *Id.* It also cites a Sixth Circuit case where the court determined that milk from rbST-treated cows is compositionally different than milk from non-rbST–treated cows. *See Int'l Dairy Foods Ass'n. v. Boggs*, 622 F.3d 628, 636–37 (6th Cir. 2010). After examining the available scientific literature regarding rbST, the court found:

> [T]he use of rbST in milk production has been shown to elevate the levels of insulin-like growth factor 1 (IGF–1), a naturally-occurring hormone that in high levels is linked to several types of cancers, among other things. The amici also point to certain studies indicating that rbST use induces an unnatural period of milk production during a cow's "negative energy phase." According to these studies, milk produced during this stage is considered to be low quality due to its increased fat content and its decreased level of proteins. The amici further note that milk from treated cows contains higher somatic cell counts, which makes the milk turn sour more quickly and is another indicator of poor milk quality. This evidence precludes us from agreeing with the district court's conclusion that there is no compositional difference between the two types of milk.

Id.

Arla also included an expert declaration from Dr. Shiv Chopra, who was responsible for reviewing the safety of rbST as the acting manager of the Human Safety Division for the Health Canada Bureau of Veterinary Drugs in 1988. Chopra Decl., ECF No. 25-2, at ¶ 4. Dr. Chopra makes similar assertions about the safety and composition of milk from rbST-treated cows to those of the Sixth Circuit: a causal link exists between rbST injections in cattle and increased production of IGF–1, a hormone linked to an increased risk of cancer and other adverse health effects in humans; it results in an increased risk of multiple births, or "twinning" in humans; and there is "substantial evidence that rbST increases rates of 16 adverse medical conditions in cows, including a clinically significant increase in mastitis, a painful inflammation of the mammary gland typically

caused by a bacterial infection." *Id.* at ¶¶ 16, 18, 22. Arla further claims that major United States retailers and consumer products brands have elected to stop using milk from cows treated with rbST, demonstrating that safety concerns about rbST are widely recognized.

In contrast, Elanco contends the available scientific literature supports a finding that rbST-treated milk is just as safe as non-treated milk. To support this proposition, Elanco relies on the testimony of Professor Robert Collier, a former Dairy Research Director at Monsanto who oversaw the development of rbST in the early 1990s. Professor Collier testified at the preliminary injunction motion hearing that rbST is safe for both cows and humans. Although some countries like Canada and Japan have banned the use of rbST, Professor Collier testified these decisions are not based on human safety concerns but rather economic considerations relevant to those countries. He further testified that while milk from cows treated with rbST does have high levels of IGF–1, there is only a transient increase that is within naturally occurring levels. Professor Collier testified there is no evidence that milk from rbST-treated cows increases cancer rates in humans, results in programmed cell death, or increases twinning. Although rbST treatments may result in a small increase in the number of mastitis infections in cows, Professor Collier testified it is incredibly rare and that there are measures in place to prevent milk from infected cows from ever reaching public consumption.

Elanco also introduced recent findings from JECFA and the FDA that refute the arguments made by Dr. Chopra and cited by the Sixth Circuit. In 2014, JECFA published a report examining the residues of specific veterinary drugs, including rbST. ECF No. 6-6. The Joint Committee determined "[a]vailable information supports the conclusions of the previous Committee that there is no significant change in the concentrations of total bST detected in milk and tissues of rbST-treated cows when compared with untreated controls." *Id.* at 73. In regard to IGF–1, it found that

"[t]reatment of cows with rbSTs transiently increased the mean IGF-I concentration in milk by up to 50%, but such increases were within the physiological variations observed in untreated cows." *Id.* Furthermore, "any carcinogenic risk from rbSTs themselves was negligible, because they are not absorbed from the gastrointestinal tract, they are not bioactive in humans and the respective orthologues did not cause cancer in rats or mice when administered subcutaneously." *Id.* at 75. JECFA ultimately concluded that "if any rbST residues are present in milk or tissues, they would pose a negligible risk to human health" and that "there was no evidence to suggest that the use of rbSTs would result in a higher risk to human health due to the possible increased use of antimicrobials to treat mastitis." *Id.* at 77–78.

In 2016, the FDA also issued a formal response to citizen petitions requesting FDA review of scientific research on Posilac®. ECF No. 6-5. The Response discussed nine main areas of concern, including whether Posilac® is toxic to treated cows and results in milk contamination; whether milk from treated cows is abnormal in composition; whether treated cows have increased IGF–1 levels in their milk which result in cancer, cell death, and increased twinning; and why rbST is banned in other countries but not the United States. *Id.* at 2. After addressing these concerns, the FDA concluded rbST "is safe and effective for its intended uses and that there is no significant difference between milk from cows treated with [rbST] and untreated cows." *Id.* at 16.

Based upon the evidence of record, I conclude that Elanco has presented strong evidence in support of its claim that there is no quantifiable difference between milk from cows treated with rbST and those that have not been treated with rbST. The most recent reviews of the underlying scientific literature on rbST—the 2014 JECFA Report and the 2016 FDA Response—conclude that rbST use is safe and does not create significant compositional differences in treated and untreated milk. While

that is not to say that the FDA or JECFA should automatically be considered as the final arbiters of truth, I find at least at this stage in the proceedings that there is a high likelihood that Elanco can demonstrate that milk from rbST-treated cows and from non-rbST–treated cows are not significantly compositionally different and are equally safe and healthy for human consumption.

2. False/Misleading Statements

Elanco asserts Arla's advertisements make at least three false statements of fact regarding rbST and milk from rbST-treated cows: "(1) that r[b]ST and r[b]ST-derived dairy products are unsafe, dangerous, or 'weird'; (2) that Arla's products are more wholesome or of better quality than dairy products made from milk of r[b]ST-supplemented cows; and (3) that r[b]ST is actually an ingredient found in some milk or dairy products." Pl.'s Br., ECF No. 7, at 20. In contrast, Arla claims that the campaign only makes "the simple representation that [Arla] cheese is not sourced from cows that have been treated with r[b]ST." Def.'s Br. in Opp'n at 15. Arla further argues that to the extent that the animated portion of its commercial suggests anything about the actual qualities of rbST, the fantastical elements make clear to a reasonable cheese consumer that he should not take any of the statements about rbST seriously.

A false statement that reaches the level of a Lanham Act violation generally falls into two categories: "(1) commercial claims that are literally false as a factual matter; or (2) claims that may be literally true or ambiguous, but which implicitly convey a false impression, are misleading in context, or likely to deceive consumers." *Hot Wax, Inc. v. Turtle Wax, Inc.*, 191 F.3d 813, 820 (7th Cir. 1999). Elanco asserts there is also a third category: literally false by "necessary implication." *See Novartis Consumer Health, Inc. v. Johnson & Johnson–Merck Consumer Pharm. Co.*, 290 F.3d 578, 586–87 (3d Cir. 2002). A statement is literally false by necessary implication when the

"consumer will unavoidably receive a false message" from the statement. *Id.* at 587. Consumer deception is presumed where advertisements are literally false or literally false by implication. *Hot Wax*, 191 F.3d at 820. On the other hand, where a statement is misleading in context, a plaintiff must demonstrate actual consumer confusion. *Id.* "[E]vidence of actual confusion must refer to the confusion of reasonable and prudent consumers, and not confusion among sophisticated members" of the industry at issue. *Platinum Home Mortg. Corp. v. Platinum Fin. Grp., Inc.*, 149 F.3d 722, 729 (7th Cir. 1998).

Arla argues the statements used in its ad campaign are not materially false but are instead "nonactionable puffery." Puffing is "exaggerated advertising, blustering, and boasting upon which no reasonable buyer would rely." *Clorox Co. Puerto Rico v. Procter & Gamble Commercial Co.*, 228 F.3d 24, 38 (2d Cir. 2000) (internal quotations and citations omitted). However, a "specific and measurable advertisement claim of product superiority . . . is not puffery." *Id.* Statements which may constitute an unspecified boast when standing alone may actually invite consumers to compare specific products when placed in context. Placing a statement in context, therefore, may transform a previously unactionable claim into a measurable claim under the Lanham Act. *Id.* at 39; *see also Pizza Hut, Inc. v. Papa John's Intern., Inc.*, 227 F.3d 489, 498–500 (5th Cir. 2000) (finding sufficient evidence to support the jury's conclusion that a non-actionable slogan was "transformed" when the advertisement compared different products). Arla asserts that the phrase "no weird stuff," as used in its advertising campaign, is a subjective claim and amounts to unactionable puffery. It further argues that the use of an obviously fantastical animation that bears no real relation to rbST is proof that no reasonable consumer could be confused about what the factual statements in its commercial are. *See Martin v. Living Essentials, LLC*, 160 F. Supp. 3d 1042, 1048 (N.D. Ill. 2016)

(holding that a commercial that claims a person was able to disprove the theory of relativity, swim the English Channel and back, find Bigfoot, and master origami while beating the record for Hacky Sack all within five hours "is an obvious farce that would not lead anyone to believe that [anyone] had actually accomplished all of the remarkable feats described").

Here, Arla's advertising campaign is neither literally false nor literally false by necessary implication. No reasonable consumer could watch Arla's commercial and conclude that rbST is *actually* a monster with razor sharp horns and electric fur. Nor does the commercial send an "unavoidable" message that rbST is dangerous—after all, it includes the FDA disclaimer that "[n]o significant difference has been shown between milk derived from r[b]ST-treated cows and non-r[b]ST-treated cows." However, based on the evidence before me, I conclude Elanco has shown a reasonable likelihood of success on the merits that Arla's advertisements make misleading misrepresentations of fact. Arla's commercial conveys the misleading message that cheese from cows treated with rbST is dangerous, unhealthy, and something that you should not feel good about feeding to your family. The advertising campaign also falsely states that rbST is an ingredient that is placed in other companies' cheese. Although the commercial ultimately explains what rbST is, the majority of the commercial implies that rbST is something frightening or alarming. The commercial ultimately explains that rbST is an artificial growth hormone given to some cows and places a very small FDA disclaimer at the bottom of the commercial. But it does nothing to dispel the false notion that cheese from cows treated with rbST is somehow dangerous. When the entire commercial is watched in context, it first creates the false impression that rbST is something foreign and dangerous, and then repeatedly emphasizes the notion that consumers should buy Arla cheese precisely because

it comes from cows untreated with rbST and does not contain any "weird stuff." This is not puffery—this is a misleading claim.

Arla notes there has already been a national and worldwide trend away from using milk from cows treated with rbST and argues that Elanco will be unable to show that any losses it incurs are caused by Arla's ad campaign. To the extent such a trend exists, there is nothing to stop Arla from alerting consumers that its products come from cows not treated with rbST and using the FDA's disclaimer in its advertisements. What Arla cannot do, however, is falsely imply or mislead consumers to believe that milk from cows treated with rbST is dangerous or otherwise unhealthy. That is precisely what Arla's commercial does. Regardless of how consumer interest is trending, advertisements may not make false or misleading statements of fact.

Elanco has also shown a reasonable likelihood that a "not insubstantial" percentage of the intended audience is likely to be misled by the advertising campaign. *See Illinois Bell Co. v. MCI Telcoms. Corp.*, No. 96-C-2378, 1996 WL 717466, at *9 (N.D. Ill. Dec. 9, 1996); *see also Novartis*, 290 F.3d at 594 ("[T]he District Court observed that even a 15.5% figure would be sufficient to demonstrate a likelihood of substantial consumer confusion."). Although Elanco has not presented any evidence of consumer survey data showing consumer deception, "such proofs are not required at the preliminary injunction stage." *Abbott Labs. v. Mead Johnson & Co.*, 971 F.2d 6, 15 (7th Cir. 1992). Given the message the advertisement conveys, it is reasonable to conclude that it is likely to cause consumer confusion and a negative reaction to products made with milk produced by cows treated with Elanco's rbST supplement. Elanco has also presented confidential information which seemingly reveals that a major cheese producer is electing to terminate the use of rbST at least in part as a result of Arla's advertising. Based on the record as it now stands, I conclude that Arla's

advertising campaign—especially the commercial on rbST—may result in a not insubstantial percentage of the intended audience concluding that milk from cows treated with rbST is unsafe, unhealthy, weird, and altogether something that you should not feel good about feeding your family. Accordingly, Elanco has shown a reasonable likelihood of success on the merits for its Lanham Act claim.

B. Remaining Injunction Factors

Although the parties largely focused on the issues of standing and the likelihood of Elanco's success on the merits, I also find that Elanco has met its burden on the remaining preliminary injunction factors. Injuries arising from Lanham Act violations are presumed to be irreparable. *See Abbott Labs.*, 971 F.2d at 16. Although Arla asserts the presumption of irreparable harm should not apply here because "[t]he advertising claims at issue . . . do not reference" Elanco or Posilac® by name, *Procter & Gamble Co. v. Ultreo, Inc.*, 574 F. Supp. 2d 339, 347 (S.D.N.Y. 2008), the advertising campaign directly focuses on rbST. Elanco is the only FDA-approved producer of rbST in the United States, thus, a reputational attack on rbST is necessarily a reputational attack on Posilac®. In addition, at least one major cheese producer has already elected to phase out its use of rbST based in part on Arla's advertising campaign. Elanco will continue to suffer unquantifiable reputational and financial damage for the length of the campaign which further supports a finding that Elanco's harm is irreparable.

The public interest also weighs in favor of issuing a preliminary injunction. Scientific studies recently reviewed by the FDA and JECFA support the conclusion that rbST-treated cows produce milk that is not substantially compositionally different than and is just as safe as milk from non-treated cows. Moreover, the recent FDA report has specifically responded to each of the objections

that have been offered to its finding that milk from rbST-treated cows is safe and is not substantially compositionally different than untreated milk. Suggesting otherwise only serves to disseminate misinformation to the public. While continued scientific research as to the safety of rbST certainly benefits the public, fear-mongering does not.

Finally, I conclude that the balance of hardships weighs in favor of issuing a preliminary injunction. Arla asserts that it will suffer substantial hardship if its campaign is pulled from television, social media, and the internet. It claims that pulling the campaign would result in a $6.5 million loss in media commitments and an estimated $9.9 million loss to create a new campaign to distribute corrective commercials. Def.'s Br. in Opp'n at 25–26. However, issuing a preliminary injunction in this case would not enjoin Arla from using the entirety of its "Live Unprocessed" advertising campaign. It would only be enjoined from using materials in the campaign that make false or misleading statements about rbST. In light of the irreparable harm facing Elanco, I cannot say Arla's hardship in possibly modifying its advertising campaign is so great as to weigh against a preliminary injunction.

Accordingly, I find that the preliminary injunction should issue. However, Elanco's request that the court order Arla to publish corrective advertisements will be denied. It is sufficient at this point in the proceedings to enjoin the false and misleading statements. Corrective advertising is more appropriately considered, if at all, after a final determination has been made.

Finally, a court "may issue a preliminary injunction . . . only if the movant gives security in an amount that the court considers proper to pay the costs and damages sustained by any party found to have been wrongly enjoyed or restrained." Fed. R. Civ. P. 65(c). Elanco proposes a security bond of $500,000. Arla asserts the cost of a preliminary injunction would result in nearly

$18,000,000 in damages. Stohrer Decl., ECF No. 25-1, at ¶ 11. No support is provided for this figure and it assumes that the entire advertising buy is lost and that Arla will be responsible for product repackaging costs. Nevertheless, bond is to be set at a sufficient amount to cover any losses if it turns out the injunction should not have issued. Based on the record as it now stands, I find that a $500,000 bond is sufficient to protect Arla at this time. Arla may move to increase the bond amount upon a more specific evidentiary showing of likely injury.

ORDER

IT IS THEREFORE ORDERED that the plaintiffs' motion for a preliminary injunction (ECF No. 4), is **GRANTED-IN-PART and DENIED-IN-PART** conditioned upon the plaintiffs' posting a bond in the amount of $500,000. The defendants, their agents or anyone else working with or on behalf of the defendants, are preliminarily enjoined and restrained, directly or indirectly, and whether alone or in concert with others from:

1. Disseminating the advertisements attached to the plaintiffs' Amended Complaint (ECF No. 10), and any other advertisement substantially similar thereto;

2. Claiming, either directly or by implication, in any advertising, website, social media, or any other type of public communication that:

   (a) rbST or Posilac®, or dairy products made from milk of cows supplemented with rbST or Posilac®, are dangerous or unsafe;

   (b) dairy products made from milk of cows supplemented with rbST or Posilac® are of lesser quality or less wholesome than, or substantially compositionally different from, other dairy products;

   (c) rbST or Posilac® is an ingredient added to some dairy products or milk;

(d) rbST or Posilac® is "weird" and/or dairy products made from milk of cows supplemented with rbST or Posilac® contain "weird stuff"; and

(e) consumers should not feel "good about eating" or "serving to [their] friends and family" dairy products made from milk of cows supplemented with rbST or Posilac®.

IT IS FURTHER ORDERED that the plaintiffs' motion is denied to the extent it seeks an order requiring the defendants to publish corrective advertisements.

IT IS FURTHER ORDERED that the plaintiffs' motion to restrict documents and for a limited protective order (ECF No. 29) is **GRANTED**.

IT IS FURTHER ORDERED that the defendants' motion to strike the plaintiffs' supplemental declaration (ECF No. 32) is **DENIED**.

Dated this 15th day of June, 2017.

s/ William C. Griesbach
William C. Griesbach, Chief Judge
United States District Court